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"510(k) Summary"
[As required by section 807.92(c)]

Prepared: January 17, 2007

Submitted by: Datrend Systems Inc.
Unit 1, 3531 Jacombs Road
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JAN 25 2007

Point of Contact: Ron Evans, extension 237.

Product Trade Name: *Phase 3 Defibrillator / Pacer Analyzer*

Common Name: Defibrillator Tester

Classification Name: Defibrillator Tester (per 21 CFR **870.5325**, Product Code **DRL**)

Substantially Equivalent to: DNI Nevada *Impulse 4000 Defibrillator / Pacer Analyzer* (listed under Applicant: HOGAN & HARTSON, 555 Thirteenth Street, NW, Washington, DC 20004), *510(k) # K941404*, (21 CFR 870.5325, Product Code DRL)

510(k) Number: K062099

Device Description

A. DEVICE DESCRIPTION:

I. *Phase 3 Defibrillator / Pacer Analyzer* is a portable, line or rechargeable battery-powered defibrillator and transcutaneous pacemaker tester. *Phase 3* is connected to the output of a defibrillator and is used to measure the energy delivered by the defibrillator into a standard resistive load. It can also provide waveform information. *Phase 3* incorporates one fixed 50 ohm test load, which roughly corresponds to the impedance of the human body, for defibrillator testing. It also includes an option to vary the test load from 25 to 175 ohms in 25 ohm steps. For pacer testing, *Phase 3* incorporates an integrated, variable internal test load, selectable from 50 ohms to 1,600 ohms in 50 ohm steps. The defibrillator paddles are connected to Phase 3 contact plates, or directly connected to the energy input if using the hands-free defibrillator function. Thus, the defibrillator is connected through the load resistance of Phase 3. When the defibrillator is discharged, *Phase 3* will calculate and display the energy delivered.

II. *Phase 3* implements connectivity through one USB Type "B" port (USB device), and through a bi-directional RS-232 port. The RS-232 port is intended for low-speed interface for data download and remote control operation, and provides the connection for an accessory Barcode Wand. The USB port is intended for high-speed interface with a PC and provides a full set of features for real-time data acquisition, remote control, and data download. Phase 3 also incorporates a non-volatile memory or "data log" to save test results or "records" obtained from multiple tests.

III. *Phase 3* optional accessories include a barcode reader and a PS/2 keyboard for rapid data entry of equipment control numbers, and a Serial Printer which may be used to generate a hard copy of test results saved in the instrument's data log. The barcode reader and printer interface with Phase 3 by means of the RS-232 Port, and a separate 6-pin mini DIN is provided on Phase 3 for the PS/2 keyboard connection.

IV. *Phase 3* conducts the following tests and includes the features listed below:

a. Energy measurements
b. Optional variable loads for energy measurements (25 – 175 ohms)
c. Cardioversion tests
d. Peak Voltage and Current measurement
e. Storage and playback of output waveforms
f. 12 lead ECG simulation
g. ECG, Performance and Arrhythmia simulation
h. Transcutaneous Cardiac Pacemaker testing
i. Automatic External Defibrillator (AED) Test procedures
j. Large Graphical display
k. Integrated Pacemaker Loads, selectable from 50 ohms to 1,600 ohms
l. RS-232, Centronics and USB (type B) communication interface

V. Principle of operation

i. *Phase 3* is a waveform analyzer that determines the characteristics of an electrical discharge signal produced by a defibrillator and/or transcutaneous pacemaker. These characteristics include: energy, peak current, peak voltage, pulse width, pulse rate, and refractory intervals.

ii. Measurements are accomplished by sampling a defibrillator signal from the defibrillator pads or from the pacer terminals at a high speed (~87ksps). Sampling is triggered by the rising or falling edge of the input. Triggering can occur at either edge to ensure that the waveform will be captured even if the operator places the defibrillator pads or connects the pacer leads in the reverse order.

iii. The defibrillator signal is digitized and stored into internal RAM. The test results are calculated based on standard numerical integration principles to determine the energy level. This process is applicable regardless of the value of the test load. These results are stored into a test record in RAM. Once all tests are completed, the user can save the test record by entering an equipment control number for identification and then transferring the record to non-volatile (NV) memory.

B. INTENDED USE / INDICATIONS FOR USE:

I. Datrend Systems Inc. *Phase 3 Defibrillator / Pacer Analyzer* is a precision instrument for ensuring that defibrillators and defibrillators with transcutaneous pacemakers comply with performance specifications.

II. *Phase 3* is connected to the output of a defibrillator and is used to measure the energy delivered by the defibrillator into a standard resistive load. It can also provide waveform information.

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III. *Phase 3*'s main function is to measure the energy output of a defibrillator. The instrument has a built-in load resistance of 50 ohms, which roughly corresponds to the impedance of the human body. The defibrillator paddles are connected to *Phase 3* contact plates, or directly connected to the energy input if using the hands-free defibrillator function. Thus, the defibrillator is connected through the load resistance of *Phase 3*. When the defibrillator is discharged, Phase 3 will calculate and display the energy delivered.

IV. The intended end user is a trained / skilled biomedical equipment technician who is required to perform incoming inspections, scheduled periodic maintenance, and repair servicing of defibrillators, both stand alone and with pacing. Such end users may be associated with public, private, or commercial institutions, including: hospitals, clinics, third-party service companies that repair or calibrate medical equipment. In general, the end user is a technically trained individual, at a post-secondary school level, specializing in medical instrumentation technology.

V. *Phase 3* is intended to be used in the laboratory environment, outside of the patient care vicinity, and is not intended to be used on patients or to test devices while connected to patients.

VI. *Phase 3* is not intended for over-the-counter use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 25 2007

Datrend Systems, Inc.
C/O Ron Evans, President
Unit 1, 3531 Jacombs Road
Richmond, BC V6V 1Z8 CANADA

Re: K062099
Trade/Device Name: Phase 3, Model # DT-1 Defibrillator / Pacer Analyzer
Regulation Number: 21 CFR 870.5325
Regulation Name: Defibrillator Tester
Regulatory Class: Class II
Product Code: DRL

Dated: January 8, 2007
Received: January 11, 2007

Dear Mr. Evans:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

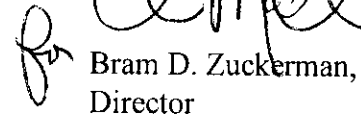
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Indications for Use

510(k) Number (if known): K062099

Device Name: ***Phase 3 Defibrillator / Pacer Analyzer***

Indications for Use:

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Phase 3 is connected to the output of a defibrillator and is used to measure the energy delivered by the defibrillator into a standard resistive load. It can also provide waveform information.

Phase 3's main function is to measure the energy output of a defibrillator. The instrument has a built-in load resistance of 50 ohms, which roughly corresponds to the impedance of the human body. The defibrillator paddles are connected to *Phase 3* contact plates, or directly connected to the energy input if using the hands-free defibrillator function. Thus, the defibrillator is connected through the load resistance of *Phase 3*. When the defibrillator is discharged, *Phase 3* will calculate and display the energy delivered.

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Phase 3 is not intended for over-the-counter use.

Prescription Use __X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K062099